

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claims 9, 11, 29, 30, 35 and 37 were rejected under 35 USC § 112, first paragraph, as claiming new matter. According to the Examiner:

“Neither the claims as filed, *nor the instant specification* disclose the step of isolating Tr1 like regulatory cells from the CD4+CD25+ T cells, as now claimed (emphasis added).”

See the last sentence of the fourth paragraph on page 4 of the final rejection. While Applicants respectfully disagree with the Examiner’s position, in order to advance the prosecution, Applicants have canceled step (b) without prejudice.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Claims 9, 11, 29, 30, 35 and 37 were rejected under 35 USC § 103(a) as being obvious over Jonuleit et al. (“Jonuleit”), *J. Exp. Med.*, 196: 255-260 (2002), in view of Nakamura et al. (“Nakamura”), *J. Exp. Med.*, 194: 629-644 (2001). In response, Applicants respectfully submit that Jonuleit is not prior art to the instant application and, therefore, respectfully request that the Examiner reconsider and withdraw this rejection.

In this regard, Applicants point out that Jonuleit has a publication date of July 15, 2002. In contrast, the present invention was completed in Germany prior to April 1, 2002. In support of this position, Applicants present the attached Declaration under 37 CFR § 1.131 of the inventors, Dr. Gerold Schuler and Dr. Detlef Dieckmann. The declaration and exhibits thereto prove the completion of the present invention prior to the publication date of Jonuleit. Therefore, Applicants respectfully submit that Jonuleit is removed as prior art against the present claims.

Further, Applicants renew their reliance on the previous Declaration under 37 CFR § 1.132 filed on October 20, 2006. The Examiner finds in the paragraph bridging pages 6-7 of the final rejection that:

“[C]ontrary to Applicant’s assertion, the Dieckmann article merely states that the article was accepted on June 5, 2002. This does not exclude the possibility that revisions might have occurred to the manuscript *before* publication.”

However, the Examiner’s position completely ignores the information provided in the last sentence of the very first paragraph on page 10 of the amendment dated January 7, 2008: “[B]oth Dieckmann and Jonuleit appeared in the *same* July 15, 2002 issue of the *Journal of Experimental Medicine*.” The Dieckmann article could not possibly have been modified *after* publication. Therefore, everything in the Dieckmann publication was, in fact, possessed by the inventors as of the publication date of the Dieckmann article of July 15, 2002. Since this is the same publication date of the Jonuleit article, the Jonuleit article does not pre-date Applicants’ possession and, therefore, cannot be prior art to the instant claims.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well. An early notice that this rejection also has been reconsidered and withdrawn is earnestly solicited.

Claims 1, 2, 7-15, 37 and 39 were rejected under 35 USC § 112, first paragraph, as claiming new matter. At the outset, Applicants point out that claims 1, 2, 8 and 9 have been canceled.

With respect to the remaining rejected claims, the Examiner finds the instant claims are not limited to “a method of inhibiting or suppressing the proliferation of T cells using TCR stimulated CD4⁺CD25⁺ T cells, as is disclosed in the prior art.” See the paragraph bridging pages 7-8 of the final rejection.

In response, Applicants respectfully submit that the support in the instant specification is much broader than merely stimulation by the TCR and, therefore, there is no reason why the instant claims should be so limited. Thus, as pointed out on page 5 of the amendment dated January 7, 2008, and conceded by the Examiner in the last paragraph on page 7 of the final rejection, instant Example 1 shows activation of CD4⁺CD25⁺ T cells with platebound anti-CD3 and soluble anti-CD28 antibodies. That same example also shows activation of CD4⁺CD25⁺ T cells with mature allogeneic DC. Accordingly, as of the time the present application was filed, Applicants clearly had possession of at least three different forms of activating CD4⁺CD25⁺ T cells, which Applicants respectfully submit is sufficient under the current patent law to support the generic term “activated.”

Moreover, Applicants again disagree with the Examiner's approach of denying written description support simply because the working examples are more detailed than the claims. Once, again, Applicants respectfully remind the Examiner that the working examples are just that—exemplary. The Examiner must consider the remainder of the disclosure, all of which is available for what it teaches persons having ordinary skill in the art.

In the instant case, the specification clearly indicates that activated CD4⁺ CD25⁺ T cells anergize CD4⁺ CD25⁻ T cells to form Tr1-like regulatory cells and, moreover, that the CD4⁺CD25⁺ T cells can be activated in a number of different ways.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well. An early notice that this rejection also has been reconsidered and withdrawn is earnestly solicited.

Finally, Applicants respectfully request rejoinder of withdrawn claims 36 and 38. According to the fifth paragraph on page 3 of the restriction requirement, “[u]pon the allowance of a generic claim, applicant *will be entitled* to consideration of claims to additional species which depend from or otherwise require all of the limitations of an allowable generic claim * * * (emphasis added).” Since claim 9 is believed to be allowable for the reasons given above, Applicants respectfully submit that the Examiner should now rejoin and consider claims 36 and 38.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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